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EXAMINER	
BEKELE, MEKONEN T	

ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,642	ROUNDHILL ET AL.	
	Examiner	**Art Unit**	
	MEKONEN BEKELE	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/16/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05/27/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 are pending in this application.

Priority

2. Applicants' claim for domestic priority under 35 U.S.C 119(e) is Acknowledge based on the Provisional Application Serial No. 60/430,226, filed on December 2, 2002.

Drawings

3. The Drawings filed on 05/27/2005 are accepted for examination.

Response to Amendment

4. Applicants' response to the last Office Action filed on 08/16/2010 has been entered and made of record.

5. Claims 1 and 12 are amended.

6. Applicants' amendment has required new grounds of rejection. New grounds rejection is therefore presented in the Office Action.

Response to Argument

7. In view of the Applicants' argument, the claims rejection under 35.U.C.S 101(claims 1-11) are expressly withdrawn.

8. Regarding claims rejection under 35.U.C.S 101(claims 12-19), the Applicants amend claim 12 by adding "a computer readable medium", and argue that the amendment overcome the 35.U.C.S 101 rejection. However, the specification on paragraph [0015] recites "the invention provides <u>a program product stored on a recordable medium</u> for optimizing ultrasound

data”. This statement of the specification can include transitory and non- transitory propagation signals, and “a transitory, propagating signal … is not a “process, machine, manufacture, or composition of matter.” Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter.” (*In re Neaten*, 84 USPQ2d 1495 (Fed. Cir. 2007)). Therefore, the examiner suggests: Amending the claims to embody the program on “**non- transitory computer-readable medium” or equivalent**; that excludes computer readable medium as a “signal”, “carrier wave”, or “transmission medium” which are deemed non-statutory.

9. Regarding claims rejection under 103(a), the Applicants’ amend the claims 1 and 12, by adding “**adjust a gain of the image acquisition system based on whether plaque is present or clutter is present**”, and argue that the applied references fail to teach or suggest the amended claims 1 and 12.

Applicants’ arguments **(**see page 9 2nd and 3rd paragraphs and page 10 1st paragraph), with respect to the rejection(s) under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the applied references and in view of Wilhjelm et al., (hereafter Wilhjelm), "*Quantitative Analysis of Ultrasound B-Mode Images of Carotid Atherosclerotic Plaque: Correlation with Visual Classification and Histological Examination*", published on December 1998, IEEE in transactions in medical imaging, Vol. 17 No. 6, pages 910-922.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 12-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 20-31 as a whole define "An ultrasound system stored in a computer readable medium… ." However, the specification on paragraph [0015] recites **"**the invention provides a program product stored on a recordable medium for optimizing ultrasound data"". This statement of the specification can include transitory and non- transitory propagation signals, and "a transitory, propagating signal … is not a "process, machine, manufacture, or composition of matter." Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter." (*In re Neaten*, 84 USPQ2d 1495 (Fed. Cir. 2007)). Therefore, the examiner suggests: Amending the claims to embody the program on "**non-transitory computer-readable medium" or equivalent**; that excludes computer readable medium as a "signal", "carrier wave", or "transmission medium" which are deemed non-statutory.

Claim Rejections - 35 USC § 103

The following is a quotation of the 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained thought the invention is not identically disclosed or described as set forth in section 102 of this title, if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-19 are rejected under 35 U.S.C 103(a) as being unpatentable over Hatfield et al. (hereafter Hatfield), US Patent No. 5840032, published on November 24, 1998 in view of Lin et al. (here after Lin), US Patent No. 5957138 published on September 28, 1999, further in view of Muzilla et al.(hereafter Muzilla), US Patent No. 6500125, field on March 30, 2000, still further view of Wilhjelm et al., (hereafter Wilhjelm), "*Quantitative Analysis of Ultrasound B-Mode Images of Carotid Atherosclerotic Plaque: Correlation with Visual Classification and Histological Examination*", published on December 1998, IEEE in transactions in medical imaging, Vol. 17 No. 6, pages 910-922.

As to claim 1, Hatfield teaches A method of capturing an image using an ultrasound system **(Abstract, Method and apparatus for three-dimensional ultrasound imaging),** comprising:

directing ultrasound waves from the ultrasound system to a body (**Abstract, ultrasound scanner collects B-mode or color flow mode images. Thus, ultrasound scanner send ultrasound wave to a patient body to collect B-mode or color flow mode images data);**

surveying the image to collect motion data **(Abstract, An ultrasound scanner collects B-mode or color flow mode images in a cine memory, i.e., for a multiplicity of slices, where the color flow mode is typically used to detect the velocity (motion) of fluid flow.**

Thus, the ultrasound scanner scans (survey) **images to collect the velocity** (motion) **of fluid flow)**;

analyzing the motion data to identify a flow in the image **(Abstract, Fig.1 element 4B, the color flow mode is typically used to detect the velocity (motion) of fluid flow. And the color flow (CF) processor 4B is used to provide a real-time two-dimensional image of blood velocity in the imaging plane by analyzing the output of the beamformer 2 data);**

scanning a limited region of the image containing the flow with a flow imaging technique**(col.4 lines 25-27, method and an apparatus for three-dimensional imaging by projecting ultrasound data acquired by scanning a volume of interest**(limited region of the image). **The ultrasound scanner collects B-mode or color flow mode images in a cine memory on a continuous basis);**

However it is noted that Hatfield does not specifically teach "the analyzing comprising segmenting the image into a flow region and a non-flow region; distinguishing plaque from clutter when low level echoes are preset "; although Hatfield teaches a method of analyzing the motion of a blood flow using a color flow processor 4B.

On the other hand the method for generating 3D images of flow structures and their flow lumen using ultrasound techniques of Lin teaches the analyzing comprising segmenting the image into a flow region and a non-flow region **(Fig. 2A step 200 and Fig.2B);**

distinguishing plaque;; when low level echoes are preset**(Fig. 4, col.7 lines 53-61, For example, imaging of flow lumen may be desired to view irregular regions that may be present in the interior of the flow structure, e.g., intimal defects, <u>plaque</u>, stenosis, etc., which may occur on the interior wall of an artery, vein, or other vessel. The irregular**

surface 404 may represent plaque, stenosis, etc. The regularity of the surface decreases the flow of blood in the vessel which generates low level ultrasound echoes).

It would have been obvious to one of ordinary skill in the art at the time of invention was made to incorporate the method of generating a border between a flow region and a non-flow region using ultrasound techniques of Lin into the method for three- dimensional imaging using ultrasound techniques of Hatfield, because both Lin and Hatfield are directed to the method for three- dimensional imaging of flow structure using ultrasound technique (Hatfield: Fig.1, col. 1 lines 65-67, Lin: Abstract, Fig.2A-2C).

It would have been obvious to one of ordinary skill in the art to incorporate the technique of three-dimensional imaging of flow structures and their flow lumen using ultrasound imaging techniques of Lin into Hatfield, because the three-dimensional imaging of ultrasound data that includes color flow data of Hatfield (Fig.1, Abstract) can be interactively-controlled to provide several types of views of a flow structure and the interior of the flow structure itself. Thus, the interior of the flow structure, including any irregularities can be viewed. Wherein, such views are especially useful in detecting branches, plaque, intimal defects, stenosis, stents, and/or any other irregular regions in arteries, veins, or other vessels (Lin: col.7 lines 53-61).

However, it is noted that both Lin and Hatfield do not specifically teaches "distinguishing;; clutter when low level echoes are preset". Specifically the combination of Lin and Hatfield do not teach distinguishing clutter since Lin et al., teaches a technique of distinguishing plaque as discussed above.

On the other hand the Ultrasound b/color priority threshold calculation of Muzilla teaches distinguishing clutter when low level echoes are preset **(Fig. 2 col.3 lines 3035, the "slow time" I/Q signal samples are passed through a wall filter 9 which rejects any clutter corresponding to stationary or very slow-moving tissue. Thu, wall filter 9 detects and rejects the clutter).**

It would have been obvious to one of ordinary skill in the art to incorporate the technique of Ultrasound b/color priority threshold calculation techniques of Muzilla into the combined method of Hatfield and Lin, because that would have allowed user of Hatfield to detect and reject cutter using the wall filter, and further would have allowed user of Hatfield to optimize display images on a display monitor (18) by automatically adjusting a threshold. B-mode data corresponding to valid color data is subjected to statistical analysis including mean and standard deviation (Muzilla: Abstract). Thus, clearly identify plaque, tissue, and vessel walls typically have a higher gray scale level than those regions containing real flow **(**Muzilla: col. 1 lines 55-58, col. 7 lines 30-35**)**;

However, it is noted that Lin, Hatfield and Muzilla do not specifically teaches “adjust a gain of the image acquisition system based on whether plaque is present or clutter is present”;

On the other hand the *Quantitative Analysis of Ultrasound B-Mode Images of Carotid Atherosclerotic Plaque of* Wilhjelm teaches “adjust a gain of the image acquisition system based on whether plaque is present **(page 913 section E, the gain level of the ultrasound scanner was adjusted for each patient so that echoes just began to appear in the blood lumen in the image of the lateral scan plane. In the present investigation a rectangular box was placed near the plaque in the unaffected lumen of the artery on the ultrasound image, as**

illustrated in Fig. 2(a). It was verified that increasing the gain resulted in an approximately linear increase in mean gray level of this box over the range of gains used. Thus, the mean level of the blood region depended on variations in gain setting from patient to patient (e.g., too high adjustment of the gain with a given attenuation of the intervening tissue layer between transducer and plaque)or clutter is present.

Hatfield and Wilhjelm are combinable because they are directed to a B-mode based ultrasound medical imaging system (Hatfield: Abstract, Wilhjelm: Abstract).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to incorporate the gain level of the ultrasound scanner of Wilhjelm (page 913, section E, lines 1-5) into the ultrasound scanner of Hatfield(Abstract) .

The suggestion/motivation for doing so would have been to adjust the gain of the ultrasound scanner with a given attenuation of an intervening tissue layer between transducer and plaque for each patient so that echoes just began to appear in the blood lumen in the image of the lateral scan plane(page 913, section E, 2nd paragraph).

Therefore, it would have been obvious to combine Wilhjelm with Hatfield to obtain the invention as specified in claim 1.

As to claim 2, Hatfield teaches surveying step comprises the step of collecting a sample of color flow data **(Abstract, An ultrasound scanner collects B-mode or color flow mode images in a cine memory, i.e., for a multiplicity of slices, where the color flow mode is typically used to detect the velocity (**motion**) of fluid flow)).**

As to claim 3, Hatfield teaches surveying step comprises the step of collecting contour data (**Abstract, col. 1 lines 15-28, An ultrasound scanner collects B-mode or color flow mode images, where the B- mode is used to image internal visual structure(contour), and color flow used to image flow characteristics, such as in blood vessels. Thus, ultrasound scanner scans** (survey) **the internal visual structure** (contour) **to collect contour data).**

As to claim 4, Lin teaches the analyzing step generates a motion map that identifies flow and non-flow regions **(Figs. 2B, 2C and 3A, for example Fig.2B shows a map that identifies a flow region 252 and a non-flow region 254).**

As to claim 5, Hatfield teaches the flow imaging technique includes a technique selected from the group consisting of: color flow **(Abstract, Fig. 1element 4B),** time domain correlation **(Abstract, the color flow velocity which is expressed in time domain ,** speckle tracking**(col.6 lines 38-35, To prevent the selection of maximum intensities which are bright speckle as opposed to desired pixel data, a filter can be used to remove such bright speckle intensities prior to projection),** strain imaging, pulse wave Doppler, and continuous wave Doppler **(Abstract, col. 1 lines 15-28, Doppler, and color flow used to image flow characteristics, such as in blood vessels).**

As to claim 6, Lin teaches the flow is associated with a valve in a heart **(col. 2 lines 7-28, the flow lumen may approximate the physical structure enclosing a flow structure, such as, for example, the interior wall(s) of an artery, vein, or other vessel).**

As to claim 7, Hatfield teaches the flow indicates a blood vessel **(co. 1 lines 5-18).**

As to claim 8, Hatfield teaches the scanning step uses multi-line beamforming **(Fig. 1. element 2 col. 3 lines 39-42, Beamformer2, the beamformer2 has multiple channels).**

As to claim 9, Lin teaches the flow is periodically tracked **(Fig.5. the flow data can be periodically track under control of user)** and the limited region of the image containing the flow is automatically adjusted **(col.7 lines 44-50, the flow region can be automatically adjusted using Keyboard for instant by the user).**

As to claim 10, Hatfield and Lin teaches the limited region for acquisition is a region selected from the group consisting of a 3D pie slice **(Hatfield: co1.4 lines 25-28, a method for three-dimensional imaging by projecting ultrasound data acquired by scanning a volume of interest. The object volume is scanned using a multiplicity of parallel slices having a substantially uniform thickness, Lin: col.6 lines 8-15),**

Further Lin teaches a cube, an arbitrary shape and a collection of shapes **(col. 2 lines 7-28, an artery, vein, or other vessel).**

As to claim 11, Hatfield teaches the scanning step includes adjusting a set of acquisition parameters **(Abstract, Fig. 1, col. 1 lines 44-53, the master controller 8 of the ultrasound imaging system accepts operator inputs through an operator)**selected from the group consisting of b-mode line densities (**Fig.1, the B- Mode Processor 4A process B- mode data and store the processed data in the B-mode Acoustic Line Memory14a)** color flow line densities**(Fig. 1, the Color Flow Processor 4B process the color flow data and store the processed color flow data in to a Color Acoustic Line Memory14B)**pulse repetition

frequency **(Abstract**, **Hatfield teaches ultrasound velocity, and** the pulse repetition frequency (prf**) is related to the ultrasound velocity. Since prf is defined as a transit time required for a plus to travel and back again at a given ultrasound velocity. Thus, Hatfield inherently teaches** the pulse repetition frequency (prf)**),** and ensemble length**(col. 1 lines 15-25, Hatfield teaches Doppler imaging system, wherein a Ensemble length by definition is the number of pulses emitted by a color Doppler imaging system to create a single line of Doppler data in the image).**

As to claim 12, Hatfield teaches an ultrasound system **(Abstract, Fig. 3; Method and apparatus for three-dimensional ultrasound imaging),** stored in a computer readable medium **(Fig. 3 element 44, Memory unit 44)** comprising:

a survey system for collecting motion data from a target image (**Abstract, An ultrasound scanner collects B-mode or color flow mode images in a cine memory, i.e., for a multiplicity of slices, where the color flow mode is typically used to detect the velocity (motion) of fluid flow. Thus, the ultrasound scanner apparatus scans (**survey**) images to collect the velocity (**motion**) of** fluid flow);

a segmentation system (**co1.4 lines 26-30, apparatus for three-dimensional imaging by projecting ultrasound data acquired by scanning a volume of interest where he object volume is scanned using a multiplicity of parallel slices having a substantially uniform thickness)** for mapping a region of flow within the image based on the motion data **(Abstract, ultrasound scanner collects B-mode or color flow images in a cine memory, i.e., for a multiplicity of slices. Thus, the color flows image data mapped on multiplicity of parallel slices regions of the image);**

a flow acquisition system **(Fig. 4b, color flow processor)** that automatically limits the collection of flow image data within the image to the region of flow**(Abstract, Fig.1, co1.1 lines 65-67, the color flow (CF) processor 4B is used to provide a real-time two-dimensional image of blood velocity in the imaging plane).**

However as discussed in claim 1 above Hatfield does not specifically teach “the segmentation system configured to segment the image into a flow region and a non-flow region”; **although Hatfield suggests the detection of color flow region using a color flow processor.**

It is also noted that Hatfield does not specifically teach “the segmentation system configured to segmenting the image into a flow region and a non-flow region; a plaque/clutter analysis system configured to distinguish between plaque and clutter, and to adjust a gain of the image acquisition system based on whether plaque is present or clutter is present ”; although Hatfield teaches a method of analyzing the motion of a blood flow using a color flow processor 4B.

On the other hand the method for generating 3D images of flow structures and their flow lumen using ultrasound techniques of Lin teaches the analyzing comprising segmenting the image into a flow region and a non-flow region **(Fig. 2A step 200 and Fig.2B);**

plaque analysis system configured to distinguish plaque **(Fig. 4, col.7 lines 53-61, For example, imaging of flow lumen may be desired to view irregular regions that may be present in the interior of the flow structure, e.g., intimal defects, <u>plaque</u>, stenosis, etc., which may occur on the interior wall of an artery, vein, or other vessel. The irregular surface 404 may represent <u>plaque</u>, stenosis, etc);**

However, it is noted that both Lin and Hatfield do not specifically teaches “clutter analysis system configured to distinguish clutter”. Specifically the combination of Lin and Hatfield do not teach distinguishing <u>clutter </u>since Lin et al. teaches a technique of distinguishing plaque as discussed above.

On the other hand the Ultrasound b/color priority threshold calculation of Muzilla teaches clutter analysis system configured to distinguish clutter **(Fig. 2 col.3 lines 3035, the "slow time" I/Q signal samples are passed through a wall filter 9 which rejects any <u>clutter</u> corresponding to stationary or very slow-moving tissue. Thu, wall filter 9 detects and rejects the clutter).**

However, it is noted that Lin, Hatfield and Muzilla do not specifically teaches “adjust a gain of the image acquisition system based on whether plaque is present or clutter is present”;

On the other hand the *Quantitative Analysis of Ultrasound B-Mode Images of Carotid Atherosclerotic Plaque of* Wilhjelm teaches “adjust a gain of the image acquisition system based on whether plaque is present **(page 913 section E, <u>the gain level of the ultrasound scanner was adjusted</u> for each patient so that echoes just began to appear in the blood lumen in the image of the lateral scan plane. In the present investigation <u>a rectangular box was placed near the plaque in the unaffected lumen of the artery on the ultrasound image</u>, as illustrated in Fig. 2(a). It was verified that <u>increasing the gain resulted in</u> an approximately linear increase in mean gray level of <u>this box over the range of gains used</u>. Thus, the mean level of the blood region depended on <u>variations in gain setting from</u>**

<u>patient to patient</u> (e.<u>g., too high adjustment of the gain with a given attenuation of the intervening tissue layer between transducer and plaque</u>) or clutter is present

Regarding claims 13-16, all claimed limitation are set forth and rejected as per discussion for claims 2, 3, 5 and 8 respectively.

Regarding claims 17-19, all claimed limitation are set forth and rejected as per discussion for claims 9-11 respectively.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Mekonen Bekele whose telephone number is 571-270-3915. The examiner can normally be reached on Monday -Friday from 8:00AM to 5:50 PM Eastern Time. If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor AHMED SAMIR can be reached on **(**571)272-7413**.** The fax phone number for the organization where the application or proceeding is assigned is 571-237-8300. Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished application is available through Privet PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866.217-919 (tool-free)

/MEKONEN BEKELE/
Examiner, Art Unit 2624
January 29, 2011

/Brian Q Le/

Primary Examiner, Art Unit 2624